

FILED WITH LRC TIME: <u>9am</u>
APR 13 2017
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1 ENERGY AND ENVIRONMENT CABINET

2 Department for Environmental Protection

3 Division of Water

4 (Amendment)

5 401 KAR 8:040. Laboratory certification.

6 RELATES TO: KRS 224.10-100, 40 C.F.R. 141.21, Appendix A-Subpart C, 141.201,
7 Appendices A, B of Subpart Q[, ~~EO-2009-538~~]

8 STATUTORY AUTHORITY: KRS 224.10-100(4), (5), (28), 224.10-110(2), 40 C.F.R.
9 141.28, 142.10, 42 U.S.C. 300f-300j-26[, ~~EO-2009-538~~]

10 NECESSITY, FUNCTION, AND CONFORMITY: KRS 224.10-110(2) requires the
11 cabinet to enforce the administrative regulations promulgated by the secretary for the regulation
12 and control of the purification of water for public and semipublic use.[~~EO-2009-538, effective~~
13 ~~June 12, 2009, establishes the new Energy and Environment Cabinet.~~] This administrative
14 regulation establishes procedures for certification of commercial or water system laboratories to
15 test for drinking water contaminants.

16 Section 1. Laboratory Certification. (1) The U.S. Environmental Protection Agency or the
17 cabinet shall evaluate a public water system laboratory or a commercial laboratory that performs
18 drinking water analysis for a public water system for certification.

19 (2) Contracting by the cabinet with a third party to conduct laboratory evaluations and
20 make recommendations to the cabinet regarding certification shall be in accordance with the

1 Manual for the Certification of Laboratories Analyzing Drinking Water; Criteria and Procedures
2 Quality Assurance; Fifth Edition, January 2005, Publication EPA 815-R-05-004, January 2005.

3 (3)(a) Certification may be for one (1) or more method analyte pair~~[analysis categories]~~
4 or for a single drinking water contaminant within a method analyte pair~~[an analysis category]~~.

5 (b) Each method analyte pair~~[analysis category]~~ shall require a different certification, but
6 qualification for different certifications may be evaluated during one (1) audit.

7 Section 2. Application. (1) An initial certification request may be made at any point
8 during the calendar year.

9 (2) A laboratory seeking certification shall submit a written request for certification to the
10 cabinet. The request shall include:

11 (a) A statement of the method analyte pair~~[analysis category]~~ or drinking water
12 contaminant for which certification is requested;

13 (b) A list of the analytic methods for each analysis for which certification is requested;

14 (c) Payment of the fee established in 401 KAR 8:050, Section 2(5) for the certification
15 requested; and

16 (d) Completion of a Proficiency Test (PT)~~[Performance Evaluation (PE)]~~ study for each
17 analysis category or drinking water contaminant for which certification is requested.

18 (3) The cabinet may request other information necessary to determine eligibility for
19 certification as described in the Manual for the Certification of Laboratories Analyzing Drinking
20 Water; Criteria and Procedures Quality Assurance; Fifth Edition, January 2005, Publication EPA
21 815-R-05-004, January 2005.

22 (4)(a) An applicant who has been decertified in accordance with the Manual for the
23 Certification of Laboratories Analyzing Drinking Water; Criteria and Procedures Quality

Assurance; Fifth Edition, January 2005, Publication EPA 815-R-05-004, January 2005 for a method analyte pair~~[an analysis category]~~ or drinking water contaminant may request recertification in accordance with this section.

(b) The applicant for recertification shall pay the fee established in 401 KAR 8:050, Section 2~~[2(4)]~~.

Section 3. Public Water System Laboratory. (1) A Public water system may establish a laboratory. Each laboratory shall be certified annually.

(2) Failure to achieve or maintain annual certification shall not relieve the public water system of the responsibility to report results of the required analyses from a certified laboratory.

Section 4. Requirements. Maintenance of certification shall require~~[the following]~~:

(1) Analysis. Analyses for drinking water contaminants shall be performed in accordance with the appropriate approved method established in 40 C.F.R. Subpart C, 141.21 through Appendix A;

(2) Submission of analysis results. The result of each analysis performed in a certified laboratory by or for a public water system shall be submitted to the cabinet by the tenth day of the month following the compliance period for which the analysis was performed and shall be submitted to the public water system as soon as possible. The public water system shall be responsible for this reporting requirement; and

(3) Proficiency Test~~[Performance evaluation]~~ sample. A Proficiency Test~~[performance evaluation (PE)]~~ sample shall be analyzed for each method analyte pair~~[analysis category]~~ or drinking water contaminant for which certification is requested, and the results shall be submitted to the cabinet at times established~~[specified]~~ in the Manual for the Certification of Laboratories Analyzing Drinking Water; Criteria and Procedures Quality Assurance; Fifth

1 Edition, January 2005, Publication EPA 815-R-05-004, January 2005 not to exceed twice a year,
2 unless additional results shall be required in accordance with the Manual for the Certification of
3 Laboratories Analyzing Drinking Water; Criteria and Procedures Quality Assurance; Fifth
4 Edition, January 2005, Publication EPA 815-R-05-004, January 2005.

5 Section 5. Deviations. (1) Deviation from accepted practice established~~[specified]~~ in the
6 Manual for the Certification of Laboratories Analyzing Drinking Water; Criteria and Procedures
7 Quality Assurance; Fifth Edition, January 2005, Publication EPA 815-R-05-004, January 2005
8 listed on a report resulting from an on-site inspection, shall be corrected.

9 (2) A written explanation of the deviation and action taken to correct it shall be submitted
10 to the cabinet within thirty (30) days of the issuance of the inspection report.

11 Section 6. Violations. (1) A laboratory shall report any violation of a maximum
12 contaminant level or other violation requiring Tier 1 public notification pursuant to 401 KAR
13 8:075~~[8:070]~~ to the public water system and the cabinet within twenty-four (24) hours of sample
14 analysis, in accordance with 40 C.F.R. 141.201-141.211, Appendices A and B.

15 (2) A public water system shall begin check sampling within twenty-four (24) hours of
16 notification of a violation.

17 (6) Emergency provision. A laboratory shall make provisions to receive and test samples
18 twenty-four (24) hours a day during an emergency.

19 Section 7. Right of Entry. A certified laboratory shall permit the cabinet to conduct on-
20 site surveys during normal business hours, without prior notification.

21 Section 8. Revocation of certification and downgrading of certification shall be in
22 accordance with the procedures established in the Manual for the Certification of Laboratories
23 Analyzing Drinking Water; Criteria and Procedures Quality Assurance; Fifth Edition, January

1 2005, Publication EPA 815-R-05-004, January 2005.

2 (1) A laboratory that has been notified of a change of certification shall, within seventy-
3 two (72) hours, notify the public water systems that the laboratory serves of the change in
4 certification status and any impact that change could have on the public water system.

5 (2) A laboratory may provide monitoring reports by subcontracting with a laboratory that
6 is certified by the cabinet.

7 Section 9. Recognition of an Out-of-state Laboratory. (1) The cabinet shall recognize a
8 laboratory located outside Kentucky upon submission of proof by the laboratory that it is
9 certified by the U.S. Environmental Protection Agency, or by a state having primary enforcement
10 responsibility for the provisions of the Safe Drinking Water Act, 42 U.S.C. 300f through 300j-
11 26, or that is certified pursuant to the Safe Drinking Water Act, 42 U.S.C. 300f through 300j-26,
12 requirements.

13 (2) A water system located in Kentucky that has entered into a contract with a certified
14 out-of-state laboratory shall comply with time intervals and capabilities established in the
15 Manual for the Certification of Laboratories Analyzing Drinking Water; Criteria and Procedures
16 Quality Assurance; Fifth Edition, January 2005, Publication EPA 815-R-05-004, January 2005.

17 (3) If on-site inspection shall be conducted for certification of an out-of-state laboratory,
18 the laboratory shall bear the cost.

19 Section 10. Incorporation by Reference. (1) "Manual for the Certification of Laboratories
20 Analyzing Drinking Water; Criteria and Procedures Quality Assurance; Fifth Edition, January
21 2005", Publication EPA 815-R-05-004, January 2005, is incorporated by reference.

22 (2) This material may be inspected, copied, or obtained, subject to applicable copyright
23 law, at the Kentucky Division of Water, 300 Sower Boulevard, Frankfort, Kentucky 40601,

1 Monday through Friday, 8 a.m. to 4:30 p.m.

401 KAR 8:040 Laboratory certification is approved for filing.


Charles G. Snavey, Secretary
Energy and Environment Cabinet

4/12/2017
Date

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall be held on Thursday, May 25, 2017 at 6:00 p.m. Eastern Time at the Department for Environmental Protection, Training Room C, 300 Sower Boulevard, Frankfort, Kentucky 40601. Individuals interested in being heard at this hearing shall notify this agency in writing by 5 workdays prior to the hearing of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through May 31, 2017. Send written notification of intent to be heard at the public hearing, or written comments on the proposed administrative regulation, to the contact person.

Contact person: Carole J. Catalfo
Internal Policy Analyst, RPPS,
Division of Water, 3rd Floor
300 Sower Boulevard
Frankfort, Kentucky 40601
Phone (502) 564-3410
Fax (502) 564-9003
Email: water @ky.gov (Subject line: "Chapter 8 regulations")

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

401 KAR 8:040

Contact Person: Carole J. Catalfo
Phone: (502) 782-6914
Email: water@ky.gov (Subject Line: "Chapter 8 regulations")

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes requirements for certified laboratories that carry out necessary analysis of drinking water.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to ensure that Kentucky has an adequate number of certified laboratories to conduct analysis for public water systems.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 224.10-110 authorizes the cabinet to enforce regulations for the purification of drinking water for public and semipublic use. 40 C.F.R. 142.10(3) requires states to have a laboratory certification program in order to maintain primacy for implementation and enforcement of the federal Safe Drinking Water Act.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation allows the cabinet to certify laboratories to carry out necessary analysis of drinking water.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: The amendments remove an outdated Executive Order and clarify materials incorporated by reference, change "Performance Evaluation" to "Proficiency Test", and "analysis category" to "method analyte pair". These changes clarify testing requirements and align them with current practice.

(b) The necessity of the amendment to this administrative regulation: The amendments to this administrative regulation clarify testing requirements and align the regulation with current practice.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 224.10-110 authorizes the cabinet to enforce regulations for the purification of drinking water for public and semipublic use. 40 C.F.R. 142.10(3) requires states to have a program for laboratory certification in order to maintain primary implementation and enforcement authority for the Safe Drinking Water Act. The amendments to this administrative regulation allow certified laboratories to use the latest analytical techniques.

(d) How the amendment will assist in the effective administration of the statutes: Public water systems and certified laboratories will be able to use the latest analytical techniques and tailor monitoring to achieve the most effective means of compliance.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: Currently there are forty-six (46) certified microbiology laboratories and fourteen (14) certified chemistry laboratories in Kentucky. Twenty-seven (27) microbiology and three (3) chemistry laboratories are municipally owned. Outside Kentucky, there are five (5) certified microbiology laboratories and twenty-four (24) certified chemistry laboratories. These laboratories serve 436 public, 52 semipublic, and 5 bottled water systems in Kentucky.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: The amendments align the regulation with current practice. No additional actions will be required for the regulated entities to comply.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): The amendments to this administrative regulation will not increase costs.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Public water systems and certified laboratories will be able to use the latest analytical techniques and tailor monitoring to achieve the most effective means of compliance.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: The amendments to this administrative regulation will not increase costs.

(b) On a continuing basis: The amendments to this administrative regulation will not increase costs.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: Funding sources will not change. Funding sources are a combination of general funds, fees, and federal funds provided to support Safe Drinking Water Act.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No

increase in fees or funding will be necessary.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation does not establish any fees directly or indirectly.

(9) TIERING: Is tiering applied? (Explain why or why not) Yes. A laboratory may be certified for a single category, a group of categories, or for all categories.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

401 KAR 8:040

Contact Person: Carole J. Catalfo
Phone: (502) 782-6914
Email: water@ky.gov (Subject Line: "Chapter 8 regulations")

(1) What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This administrative regulation applies to certified laboratories that perform analysis for contaminants in public and semipublic water systems. Public water systems are often owned by city governments or organized under county governments. Other entities, such as associations, privately-owned or investor-owned entities, may have a water system.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 224.10-100 authorizes the cabinet to enforce regulations for the purification of drinking water for public and semipublic use. 40 C.F.R. 142.10(3) requires that the cabinet have a laboratory certification program as a condition of maintaining primary implementation and enforcement authority for the Safe Drinking Water Act.

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation will not generate any revenue.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation will not generate any revenue.

(c) How much will it cost to administer this program for the first year? This administrative regulation will not result in additional costs.

(d) How much will it cost to administer this program for subsequent years? This administrative regulation will not result in additional costs.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): NA

Expenditures (+/-): NA

Other Explanation: This administrative regulation will not have any additional fiscal impact.

FEDERAL MANDATE ANALYSIS COMPARISON

401 KAR 8:040

Contact Person: Carole J. Catalfo
Phone: (502) 782-6914
Email: water@ky.gov (Subject Line: "Chapter 8 regulations")

1. Federal statute or regulation constituting the federal mandate. 40 C.F.R. 142.10(3)
2. State compliance standards. KRS 224.10-110
3. Minimum or uniform standards contained in the federal mandate. 40 C.F.R. 142.10(3) requires states to have a laboratory certification program as a condition for maintaining primary implementation and enforcement authority for the Safe Drinking Water Act.
4. Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements than those required by the federal mandate? This administrative regulation does not impose stricter, additional, or different requirements from the federal mandate.
5. Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements. This amendment does not impose stricter standards, or additional or different responsibilities or requirements.

Detailed Summary of Material Incorporated by Reference

I. This administrative regulation incorporates by reference the “Manual for the Certification of Laboratories Analyzing Drinking Water; Criteria and Procedures Quality Assurance; Fifth Edition, Publication EPA 815-R-05-004, January 2005.” This document is used to determine eligibility for laboratory certification, accepted laboratory practices, and reporting time intervals and capabilities. This document is the most current edition.

This document consists of 209 pages.